

AMENDMENTS TO THE CLAIMS

Please CANCEL Claims 15-22, 25-26, 28-29, 31-32, 34, 36 and 38.

B1
1. **(Previously Canceled)** A pharmaceutical composition that reduces wake after sleep onset, increases total sleep time, increases sleep efficiency, or increases sleep time spent in sleep stages three and four, in normal adults comprising:

therapeutically effective amounts of valerenic acid and its derivatives, kessane derivatives, valeranone, valeranal, and amino acids prepared by (i) adding the roots to an alcoholic extraction solvent to form a mixture, wherein the alcoholic extraction solvent comprises between approximately 50% (v/v) to approximately 100% (v/v) ethanol in a remainder of water, and (ii) heating the mixture to a temperature of between approximately 70°C to approximately 80°C for a period of at least two hours; wherein valerenic acid is present in the extract, the content of valepotriates in the extract is substantially reduced with respect to its content in the root, and the content of valerenic acids in the extract is not substantially reduced with respect to its content in the root; and minimizing the yield of unstable valepotriates.

2. **(Previously Canceled)** The pharmaceutical composition according to Claim 1, wherein the therapeutically effective amount of extract is between about 50 mg and about 5000 mg.

3. **(Previously Canceled)** The pharmaceutical composition according to Claim 1, wherein the therapeutically effective amount of valerenic acid is between about 150 µg and about 15 mg.

4. **(Previously Canceled)** The pharmaceutical composition according to Claim 1, wherein the therapeutically effective amount of valerenic acid is between about 0.3 mg and about 15 mg.

5. **(Previously Canceled)** The pharmaceutical composition according to Claim 1, wherein the valerenic acid derivative is acetoxylvalerenic acid.

6. **(Previously Canceled)** The pharmaceutical composition of Claim 5, wherein the therapeutically effective amount of acetoxylvalerenic acid is between about 0.2 mg and about 20 mg.

Appl. No. : 10/029,109
Filed : October 19, 2001

7. **(Previously Canceled)** The pharmaceutical composition of Claim 5, wherein the therapeutically effective amount of acetoxvaleronic acid is between about 0.4 mg and about 20 mg.
8. **(Previously Canceled)** The pharmaceutical composition according to Claim 1, wherein the valeronic acid derivative is hydroxyvaleronic acid.
9. **(Previously Canceled)** The pharmaceutical composition of Claim 8, wherein the therapeutically effective amount of hydroxyvaleronic acid is between about 5 μ g and about 0.5 mg.
10. **(Previously Canceled)** The pharmaceutical composition of Claim 8, wherein the therapeutically effective amount of hydroxyvaleronic acid is between about 10 μ g and about 50 μ g.
11. **(Previously Canceled)** The pharmaceutical composition according to Claim 1, wherein the valeronic acid derivative is valeranal.
12. **(Previously Canceled)** The pharmaceutical composition according to Claim 11, wherein the therapeutically effective amount of valeranal is between about 20 μ g and about 2 mg.
13. **(Previously Canceled)** The pharmaceutical composition according to Claim 1, wherein the valeronic acid derivative is valeranol.
14. **(Previously Canceled)** The pharmaceutical composition according to Claim 13, wherein the therapeutically effective amount of valeranol is between about 0.5 μ g and about 50 μ g.
15. **(Canceled)** A method of reducing the number of wakings after sleep onset in a patient comprising:
- administering a pharmaceutically-active extract of the root of a plant of the family Valerianaceae to the patient;
 - administering the extract in a single dosage between about 50 mg and about 5000 mg;
 - delivering the dosage to the patient between approximately one-half and approximately two hour before bedtime; and

delivering the dosage for at least two consecutive nights.

16. **(Canceled)** The method of Claim 15, wherein the dosage is deliver at about one hour before bedtime.

17. **(Canceled)** The method of Claim 15, wherein the dosage is deliver at between about one half and one and one-half hour before bedtime.

18. **(Canceled)** The method of Claim 15, wherein the root of a plant of the family Valerianaceae is *Valeriana officinalis L.*

19. **(Canceled)** A method of reducing the length of wakings after sleep onset in a patient comprising:

administering a pharmaceutically-active extract of the root of a plant of the family Valerianaceae to the patient;

administering the extract in a single dosage between about 50 mg and about 5000 mg;

delivering the dosage to the patient between approximately one-half and approximately two hour before bedtime; and

delivering the dosage for at least two consecutive nights.

20. **(Canceled)** The method of Claim 19, wherein the dosage is deliver at about one hour before bedtime.

21. **(Canceled)** The method of Claim 19, wherein the dosage is deliver at between about one half and one and one-half hour before bedtime.

22. **(Canceled)** The method of Claim 19, wherein the root of a plant of the family Valerianaceae is *Valeriana officinalis L.*

23. **(Original)** A method of reducing the number of wakings after sleep onset in a patient comprising:

(a) administering to the patient a pharmaceutically-active extract of the root of a plant of the family Valerianaceae processed by:

adding the roots to an alcoholic extraction solvent to form a mixture, wherein the alcoholic extraction solvent comprises between approximately 50% (v/v) to approximately 100% (v/v) ethanol in a remainder of water, and

heating the mixture to a temperature of between approximately 70°C to approximately 80°C for a period of at least two hours; wherein valerenic acid is present in the extract, the content of valepotriates in the extract is substantially reduced with respect to its content in the root, and the content of valerenic acids in the extract is not substantially reduced with respect to its content in the root;

(b) administering the extract in a single dosage between 50 mg and 5000 mg; and

(c) delivering the dosage to the patient between approximately one-half and two hours before bedtime.

24. (Original) A method of reducing the length of wakings after sleep onset in a patient comprising:

(a) administering to the patient a pharmaceutically-active extract of the root of a plant of the family Valerianaceae processed by:

adding the roots to an alcoholic extraction solvent to form a mixture, wherein the alcoholic extraction solvent comprises between approximately 50% (v/v) to approximately 100% (v/v) ethanol in a remainder of water, and

heating the mixture to a temperature of between approximately 70°C to approximately 80°C for a period of at least two hours; wherein valerenic acid is present in the extract, the content of valepotriates in the extract is substantially reduced with respect to its content in the root, and the content of valerenic acids in the extract is not substantially reduced with respect to its content in the root;

(b) administering the extract in a single dosage between 50 mg and 5000 mg; and

(c) delivering the dosage to the patient between approximately one-half and two hours before bedtime.

25. (Canceled) A method of increasing total sleep time comprising:

administering a pharmaceutically-active extract of the root of a plant of the family Valerianaceae to a patient;

administering the extract in a single dosage between 50 mg and 5000 mg;

delivering the dosage to the patient approximately one-half and two hour before bedtime; and

delivering the dosage for at least two consecutive nights.

26. **(Canceled)** The method of Claim 25, wherein the root of a plant of the family Valerianaceae is *Valeriana officinalis* L.

~~27~~ **(Original)** A method of increasing total sleep time comprising:

(a) administering to a patient a pharmaceutically-active extract of the root of a plant of the family Valerianaceae processed by:

adding the roots to an alcoholic extraction solvent to form a mixture, wherein the alcoholic extraction solvent comprises between approximately 50% (v/v) to approximately 100% (v/v) ethanol in a remainder of water, and

heating the mixture to a temperature of between approximately 70°C to approximately 80°C for a period of at least two hours; wherein valerenic acid is present in the extract, the content of valepotriates in the extract is substantially reduced with respect to its content in the root, and the content of valerenic acids in the extract is not substantially reduced with respect to its content in the root.

(b) administering the extract in a single dosage between 50 mg and 5000 mg; and

(c) delivering the dosage to the patient approximately one-half and two hour before bedtime.

28. **(Canceled)** A method of increasing sleep efficiency comprising:

administering a pharmaceutically-active extract of the root of a plant of the family Valerianaceae to a patient;

administering the extract in a single dosage between 50 mg and 5000 mg;

delivering the dosage to the patient approximately one half and two hours before bedtime; and

delivering the dosage for at least two consecutive nights.

29. **(Canceled)** The method of Claim 28, wherein the root of a plant of the family Valerianaceae is *Valeriana officinalis* L..

~~30~~ **(Original)** A method of increasing sleep efficiency comprising:

(a) administering to a patient a pharmaceutically-active extract of the root of a plant of the family Valerianaceae processed by:

adding the roots to an alcoholic extraction solvent to form a mixture, wherein the alcoholic extraction solvent comprises between approximately 50% (v/v) to approximately 100% (v/v) ethanol in a remainder of water, and

heating the mixture to a temperature of between approximately 70°C to approximately 80°C for a period of at least two hours;

wherein valerenic acid is present in the extract, the content of valepotriates in the extract is substantially reduced with respect to its content in the root, and the content of valerenic acids in the extract is not substantially reduced with respect to its content in the root.

(b) administering the extract in a single dosage between 50 mg and 5000 mg; and

(c) delivering the dosage to the patient approximately one-half and two hours before bedtime.

31. **(Canceled)** A method of increasing sleep time spent in sleep stages three and four comprising:

administering a pharmaceutically-active extract of the root of a plant of the family Valerianaceae to a patient;

administering the extract in a single dosage between 50 mg and 5000 mg;

delivering the dosage to the patient approximately one-half and two hours before bedtime; and

delivering the dosage for at least two consecutive nights.

32. **(Canceled)** The method of Claim 31, wherein the root of a plant of the family Valerianaceae is *Valeriana officinalis* L.

33. **(Original)** A method of increasing sleep time spent in sleep stages three and four comprising:

(a) administering to a patient a pharmaceutically-active extract of the root of a plant of the family Valerianaceae processed by:

adding the roots to an alcoholic extraction solvent to form a mixture, wherein the alcoholic extraction solvent comprises between approximately 50% (v/v) to approximately 100% (v/v) ethanol in a remainder of water, and

heating the mixture to a temperature of between approximately 70°C to approximately 80°C for a period of at least two hours; wherein valerenic acid is present in the extract, the content of valepotriates in the extract is substantially reduced with respect to its content in the root, and the content of valerenic acids in the extract is not substantially reduced with respect to its content in the root.

(b) administering the extract in a single dosage between 50 mg and 5000 mg; and

(c) delivering the dosage to the patient approximately one-half and two hours before bedtime.

34. **(Canceled)** A method of Claim 17, wherein the dosage is delivered for at least three consecutive nights.

35. **(Original)** A method of Claim 24, wherein the dosage is delivered for at least five consecutive nights.

36. **(Canceled)** A method of Claim 28, wherein the dosage is delivered for at least seven consecutive nights.

37. **(Previously Canceled)** The composition of Claim 1, wherein the pH of the mixture is maintained above approximately 3.0.

38. **(Canceled)** The method of Claim 15, wherein the pH of the mixture is maintained above approximately 3.0.